K082762

510(k) Summary
Prepared August 30, 2008
Revised November 6, 2008

NOV 12 2008

Submitted by: Aardvark Medical, Company
P.O. Box 1654
Ross, Califirnia 94957

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Product Name: Aardvark nasal irrigation and aspiration device

Common Name: Powered Nasal Irrigator and Aspirator

Classification: Powered Nasal Aspirator 874.5550 Class I
Powered Portable Suction 878.4780 Class II

Predicate Devices:

Device Name	Manufacturer	K Number
Rhinoflow Micronized ENT Wash System	Respironics	K973875
Orwell Fluid Collections and Disposal System	Cardinal Health	K989845
DeVilbiss Suction Device	Sunrise Medical	K982304
The EMG suction Unit	EMG Technology Company	K063448

Description of Device:
The Aardvark device is designed to make nasal and sinus lavage easy and convenient. The device facilitates instillation of saline into the nasal passage. It then provides mild powered suction to remove the fluid from the nostril. Alternatively, it can be used on the opposite nostril while intermittently occluding the sprayed nostril, i.e., the Proetz Displacement maneuver. The device consists of a hand held battery operated unit with a disposable tip portion. A charger is provided with the device.

Intended Use:
The Aardvark Medical Device is intended for use in nasal and sinus lavage. The device facilitates instillation of saline into the nasal passage and provides powered suction to either 1) directly evacuate the nasal passage, or 2) to remove the fluid and effluent by aspirating from the opposite nostril in a maneuver similar to the Proetz displacement or aspiration irrigation maneuver. The device is used to treat conditions and disorders of the upper respiratory tract where homeostasis of the nasal mucosa is disturbed, resulting in symptoms such as catarrh and mucopurulent or crust secretions. Such conditions and disorders include: Rhinitis (as a symptom of colds, allergies, etc.) and both acute and chronic Sinusitis It can also be used to collect mucus samples for subsequent testing. It is intended for use in adults and children in either the physician's office or in the home.

Comparison with Predicate Devices:
The submission device and the predicate devices have substantially equivalent intended use and technological specifications.

Performance:
The Aardvark device verification testing under the company's Design Control Process has confirmed the device's conformance with specifications. The specifications do not include any significant differences from those of the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aardvark Medical Company
c/o Marc Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

NOV 12 2008

Re: K082762
Trade/Device Name: Aardvark Nasal Irrigation and Aspiration System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: October 28, 2008
Received: October 29, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Aardvark Nasal Irrigation and Aspiration System

Indications For Use:

The Aardvark Medical Device is intended for use in nasal and sinus lavage. The device facilitates instillation of saline into the nasal passage and provides powered suction to either 1) directly evacuate the nasal passage, or 2) to remove the fluid and effluent by aspirating from the opposite nostril in a maneuver similar to the Proetz displacement or Aspiration Irrigation Maneuver. The device is used to treat conditions and disorders of the upper respiratory tract where homeostasis of the nasal mucosa is disturbed, resulting in symptoms such as catarrh and mucopurulent or crust secretions. Such conditions and disorders include: Rhinitis (as a symptom of colds, allergies, etc.) and both acute and chronic Sinusitis. It can also be used to collect mucus samples for subsequent testing. It is intended for use in adults and children in either the physician's office or in the home.

Prescription Use____X____ OR Over-The-Counter Use _____
(Per 21CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____Concurrence Of CDRH, Office Of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

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